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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHENG, JACQUELINE

ART UNIT

PAPER NUMBER

3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,934	Applicant(s) DESMEDT ET AL.	
	Examiner JACQUELINE CHENG	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/14/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on September 16, 2003 and on July 10, 2003. It is noted, however, that applicant has not filed a certified copy of the September 16, 2003 (03103405.1) application as required by 35 U.S.C. 119(b).

Claim Objections

2. **Claims 1-13** are objected to because of the following informalities: It is suggested that all instances of “characterized in that” be changed to --wherein-- to conform better with US patent application language.

3. **Claims 1-4, 9, 10, and 13** are objected to because of the following informalities: It is suggested that all instances of “is arranged to” be changed to --is configured to-- to properly claim that the processing unit has the certain structure for carrying out the particular function versus it only being functional language as any processing unit is capable of being arranged to perform whatever function is desired.

4. **Claim 4** is objected to because of the following informalities: It is suggested that “the registration” on the 4th line of the claim be changed to --the 2D-3D registration-- to stay consistent with claim 3.

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5. **Claim 7** is objected to because of the following informalities: It is suggested that “the 2D-images of the instrument” on the 2nd line of the claim be changed to --the acquired 2D-images of the instrument-- to stay consistent with claims 5 and 7.

6. **Claim 11** is objected to because of the following limitations: It is suggested that “acquired images of the instrument” in the 2nd to last line of the claim be changed to --acquired 2D images of the instrument-- to stay consistent with claims 9 and 11.

7. **Claim 13** is objected to because it is unclear if it is the data carrier, the software for a computer, or the apparatus for navigating an instrument through an anatomical structure that is arranged to implement the steps.

8. Appropriate corrections are required.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. **Claims 9-13** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Data structures (such as software) not claimed as embodied in computer-readable media are descriptive material *per se* and are not statutory because they are not capable of causing functional change in the computer. Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer software and

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hardware components which permit the data structure's functionality to be realized, and is thus statutory (MPEP 2106-IV-B-1-(a) pg. 2106).

11. It is suggested that the claim language of claims 9 and 13 be changed to state --A computer readable medium having, stored thereon, computer executable software for navigating an instrument through an anatomical structure of a patient's body volume, the software comprising instructions for causing a computer to implement the steps of:-- or an equivalent thereof and that the claim language of claims 10-12 be changed to state --The software stored on the computer readable medium according to claim [9, 11] further comprising instruction for causing the computer to further implement the steps of:-- or an equivalent thereof.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. **Claim 2** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how a 2d-3d registration is done on two series of 2D images. It is suggested the applicant meant --2D-3D registration of the coordinates of the 3D-images of the anatomical structure in respect to both the first series and the second series of 2D-images of the instrument--.

14. **Claims 2, 6, and 10** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. It is not believed that the applicant's invention creates both a merged 3D-image of the instrument comprised of the 2D-images of the instrument and the 3D images of the anatomical structure (claim 1) AND an image from merging a 3D image of the instrument with the 3D image of the anatomical structure (claim 2 dependent on claim 1). It is believed that the invention as disclosed in the specification creates EITHER a merged image of the 2D instrument image and the 3D anatomical image if the system has only one C-arm (claim 1) OR a merged image of the created 3D instrument image and the 3D anatomical image if the system has two C-arms (claim 2).

15. **Claims 3, 7, and 11** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not believed that the applicant's invention creates both a merged 3D-image of the instrument comprised of the 2D-images of the instrument and the 3D images of the anatomical structure (claim 1) AND an image from merging an adapted 3D model representation of the instrument with the 3D image of the anatomical structure (claim 3). It is believed that the invention as disclosed in the specification creates EITHER a merged image of the 2D instrument image and the 3D anatomical image if the system (claim 1) OR a merged image of an adapted 3D model representation of the instrument image and the 3D anatomical image (claim 3).

16. **Claims 4, 8 and 12** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not believed that the applicant's invention creates all three of a merged 3D-image of the instrument comprised of the 2D-images of the instrument and

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the 3D images of the anatomical structure (claim 1) AND an image from merging an adapted 3D model representation of the instrument with the 3D image of the anatomical structure (claim 3) AND an image from merging an adapted 3D image model representation of the instrument from both a first and second series of 2D images with the 3D image of the anatomical structure (claim 4). It is believed that the invention as disclosed in the specification creates either a merged image of the 2D instrument image and the 3D anatomical image if the system has one C-arm (claim 1) OR a merged image of an adapted 3D model representation of the instrument image and the 3D anatomical image if the system has one C-arm (claim 3) OR a merged image of an adapted 3D model representation of the instrument from a first and second series of 2D images of the instrument and the 3D anatomical image representation if the system has two C-arms.

17. Claims 4, 8, and 12 recite the limitation "this/the/the adapted 3D-model representation" in the 2nd to last lines/2nd to last line/last line of the claim. There is an antecedent basis issue for this limitation in the claim. It is uncertain if "this/the/the adapted 3D-model representation is referring to the adapted 3D-model representation in claim 4/8/12 or the adapted 3D-model representation in claim 3/7/11.

18. **Claim 4** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how an adapted 3D-model representation is created without using the 3D-model representation. As the claim is currently written the adapted 3D-model representation is created only from the first series and the second series of the 2D-images of the instrument.

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19. **Claim 7, 8, and 11** recite the limitation "the matching" in the 3rd to last line of the claim, 4th to last line of the claim, 3rd to last line of the claim respectfully. There is insufficient antecedent basis for this limitation in the claims.

20. **Claims 7 and 11** recites the limitation "prior to merging the adapted 3D-model representation of the instrument with the 3D anatomical structure" in the last 2 lines of the claim. There is insufficient antecedent basis for this limitation in the claim as no step of merging the adapted 3D-model representation of the instrument with the 3D anatomical structure has been previously claimed.

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

22. **Claims 1, 5, 9, and 13** are rejected under 35 U.S.C. 102(a) as being anticipated by Strobel (US 7,050,844 B2). Strobel discloses a method and apparatus for detecting the 3D position of an instrument in a body volume. The apparatus comprises a bed for the patient, and an image registration and calculating unit (processing unit and memory device), and two C-arm systems each with a X-ray source and X-ray detector (fig. 3). As to the process, first a 3D angiography of the examination region (pre-determined 3D-images of a patient's anatomical structure) is taken and stored for later use. Subsequently an instrument such as a catheter is introduced and then 2D projection image taken with the two C-arms at orthogonal angles to one

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another (first and second series of 2D-images of the instrument) are taken each of which are registered with the 3D angiography image to a common coordinate system (2D-3D registration). As a last step the 2D projection images are merged with the 3D angiography images (merged 3D-images of the instrument) and displayed so that the physician can see the spatial position of the catheter tip as well as the spatial course of the vessel (fig. 1, col. 2 line 35-col.3 line 34, col. 5 line 62-col. 6 line 26).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. **Claims 2, 6, and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel further in view of Hall (US 2003/0181809 A1). Strobel discloses most of what is claimed as discussed above except for creating a 3D-image of the instrument. In the same field of

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endeavor Bani-Hashemi discloses a method for detecting a 3D location of an instrument wherein a 3D image of the instrument is combined with the 3D angiographic image (col. 7 line 30-40, col. 8 line 45-47). It would be obvious to one skilled in the art to create a 3D image of the instrument from the 2D images of the instrument of Storbel and use this image of the instrument to combine with the 3D angiographic images for the purpose of allowing the physician to have a full and complete 3D view of the catheter position and orientation versus the 2D image which would only be a point representing the catheter.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2003/0181809 A1 to Hall, US 7,302,286 B2 to Camus, and US 6,317,621 B1 to Graumann.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768